

REMARKS

By way of summary, claims 1, 26 and 27 have been amended. Claims 15-25 and 28 have been cancelled. Claims 2-7, 9-10 and 12 were previously canceled. Accordingly, claims 1, 8, 11, 13, 14 and 26-27 are now presented for examination on the merits.

Rejection of Claims 1, 8, 11, 13 and 14 under 35 USC §112

Claims 1, 8, 11, 13 and 14 have been rejected as failing to comply with the written description requirement. More particularly, page 2 of the Office Action states that the phrase "wherein the coronary sinus has a natural curvature, the curvature of the second shape being different than the natural curvature of the coronary sinus" is not disclosed in the specification.

By way of background, the present application discloses an implantable elongate body that treats mitral insufficiency (i.e., regurgitation) caused by dilatation (i.e., enlargement) of the mitral annulus. The implantable elongate body is delivered without the need for cardiopulmonary by-pass and without opening the chest and heart. The implantable elongate body is delivered into the coronary sinus and is adjusted to alter the curvature of the coronary sinus. By changing the curvature of the coronary sinus, the shape of the mitral valve annulus is changed in a manner which improves the function of the mitral valve, thereby reducing undesirable regurgitation through the mitral valve.

More particularly, the Abstract of the present application states:

"A device for treatment of mitral annulus dilatation comprises an elongate body having two states. In a first of these states the elongate body is insertable into the coronary sinus and has a shape adapting to the shape of the coronary sinus. When positioned in the coronary sinus, the elongate body is transferable to the second state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus and the radius of curvature as well as the circumference of the mitral annulus is reduced."

As stated in the Abstract and throughout the specification, the elongate body has a first state configured for insertion into the coronary sinus wherein the elongate body has a shape adapting to the shape of the coronary sinus. The Abstract further states that the elongate body is transferable to a second state assuming a reduced radius of curvature whereby the curvature of the coronary sinus is reduced. Therefore, after the elongate body has been transferred to the second state, the coronary sinus has a second shape that is different than the natural curvature of the coronary sinus.

Although Applicant believes there is support for the claim language as previously written, Applicant has amended claim 1 to recite "wherein changing the mitral valve annulus device from the first shape to the second shape affects the radius of curvature of the coronary sinus." The new language more closely tracks the precise language of the specification. For example, see paragraph [0014] of the present application.

To expedite examination, Applicant has also canceled dependent claim 28 which has similar language regarding changing a "natural curvature of the coronary sinus."

Accordingly, Applicant believes that the rejections under 35 USC §112 have been overcome.

Rejection of Claims 1, 8, 11, 13, 14 and 26-28 under 35 USC §102

Claims 1, 8, 11, 13, 14 and 26-28 have been rejected under 35 USC §102(b) as being anticipated by Mehra (U.S. Patent No. 5,170,802).

To clarify the features of the claimed invention, Applicant has amended independent claim 1 to further recite "a forming element coupled to the mitral valve annulus device, the forming element extending proximally to a location outside the body for adjusting the curvature of the mitral valve annulus device." There is no teaching or suggestion in Mehra of a forming element for manipulating a device from a location outside the venous system. Rather, Mehra merely discloses an implantable electrode structure. The electrode structures are configured to conform to the shape of the body structure in which they are implanted. It is not possible to adjust the curvature of the electrode disclosed by Mehra to alter a curvature of the coronary sinus.

Applicant has also amended independent claim 26 to recite "a resilient mitral valve annulus device configured to be received on the guide wire and advanced into the coronary

sinus, the mitral valve annulus device being transferable to a different radius of curvature for selectively altering a curvature of the coronary sinus” and “at least one forming element coupled to the mitral valve annulus device for manipulating the radius of curvature of the mitral valve annulus device from a location outside the venous system.”

There is no teaching or suggestion in Mehra of a mitral valve annulus device being transferable to a different radius of curvature for selectively altering a curvature of the coronary sinus. Mehra also fails to teach or suggest a forming element coupled to the mitral valve annulus device for manipulating the curvature of the mitral valve annulus device from a location outside the venous system.

Accordingly, Applicant believes that all rejections under 35 USC §102(b) have been overcome and the pending claims are now in condition for allowance.

Fees Due to File This Amendment

Prior to the pending Office Action, a fee was paid for 20 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the number of claims originally paid for, and **thus no claim fees are believed to be due** to file this amendment.

Petition for Extension of Time to Respond

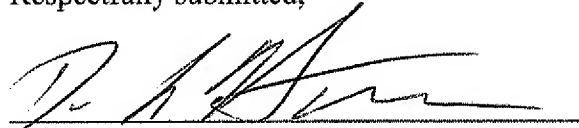
Pursuant to 37 C.F.R. 1.136(a), Applicant hereby requests an extension of time for **Two Months** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$460.00 to Deposit Account No. 50-1225 (Docket No. PVI-5697CIPCON).

Conclusion

Should the Examiner have any remaining questions, the Examiner is encouraged to contact the attorney of record at the telephone number shown below.

Date: March 14, 2008

Respectfully submitted,



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